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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,703	03/17/2006	Markus Storr	52759-215213	5360

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EXAMINER	
MELLON, DAVID C	
ART UNIT	PAPER NUMBER
1777	

NOTIFICATION DATE	DELIVERY MODE
04/12/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

indocket@btlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/572,703	STORR ET AL.	
	Examiner	Art Unit	
	DAVID C. MELLON	1777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/11/2011 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 67-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 67-69 provides for the use of a separating material, but, since the claim does not set forth ay steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 67-69 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Interpretation

6. Regarding the method limitations recited in at least claim(s) 40-53 the examiner notes that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated in Thorpe, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. In re Pilkington, 411 F.2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.).

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 40-66, 80-82, 84-86, and 89-96, are rejected under 35 U.S.C. 103(a) as being unpatentable over Horl et al. (USP 5,556,708) in view of Pitt et al. (USP

5,037,656) and evidenced by Drumheller (Surface Immobilization of Adhesion Ligands for Investigations of Cell-Substrate Interactions).

Regarding claims 40-41, 43-51, 53-54, 56-64, 66, 80, 82, 84-85, 89-94, and 96, Horl et al. discloses a process for grafting of polymers and polymers obtained thereby (Title) comprising:

- Providing a solid substrate having a substrate surface wherein amino functional groups are coupled to the substrate surface and formed as a membrane or fibers (C5/L10-20 – substrate, specifically "polyamides", C5/L40-45 – primary amino groups which are biocompatible, C7/L1-19 - fibers, membranes);
- Covalently coupling the amino functional groups with a reducing agent (C8/L1-15, C11/L28-33 – the reducing agent would couple covalently with the amino functional groups due to chemical attraction when exposed in an aqueous or liquid environment with the reducing agent and utilizing a thermal activation, C11/L43-50 - furthermore see Drumheller on P7 - "Immobilization to Surface Amines" which discusses several compounds to bind chemicals with surface amines - it is considered that the covalent coupling is an inherent intermediate product to produce the final product - the mere fact that the mechanism of Horl is unknown does not further patentability. Further, Drumheller clearly indicates an equivalent mechanism using similar circumstance; albeit more generic to the end product);

- Contacting the substrate surface with a solution of polymerizable monomers wherein graft copolymerization of the monomers forms a structure of adjacent functional polymer chains on the substrate surface (C6/L15-60, specifically see also C8/L2-44).

Horl et al. does not disclose the use of a thermally labile radical initiator to promote the polymer grafting process.

Pitt et al. discloses a composite porous membrane formed from a porous polymer membrane (Abstract) comprising:

- Providing a porous membrane (C3/L1-5)
- Covalently coupling a thermally labile radical initiator to the membrane (C4/L30-40 – see exemplary compounds, specifically "4,4'-azobis-(4-cyanovaleric acid)" - also see C3/L58-66)
- Contacting the substrate surface with a polymerizable monomer solution (C4/L12-28 – see exemplary monomers, see also C3/L58-67).

Horl et al. and Pitt et al. are combinable because they are concerned with the same field of endeavor, namely that of graft polymerization membrane structures.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the membrane and process of Horl et al. to use an azo compound such as 4,4'-azobis-(4-cyanovaleric acid) as a thermally labile radical initiator to promote graft polymerization as taught by Pitt et al. for the purpose of providing a more effective, rapider polymerization process to eliminate the need for additional crosslinking agents when using a functionalized substrate (see also Pitt C3/L1-11).

Specifically regarding claims 40-41, Applicant is noted that the claim is a product-by-process type claim. Accordingly, it is asserted that the wash step of claim 41 does not further limit the structure or provide an unexpectedly different structure. Accordingly, Applicant must either further define the product or provide evidence of its difference from that of the prior art. Regarding the method limitations recited in claim(s) 40-41, the examiner notes that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated in Thorpe, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. In re Pilkington, 411 F.2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.).

Regarding claims 42, 55, and 81, modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. further discloses that the nylon 6,6 support membranes are discloses as having a pore diameter of 0.2 micrometers which would be sufficient to allow the passage of blood serum (C20/L15-25, C21/L45-50).

Regarding claims 52, 65, and 95, modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. does not explicitly set forth the use of dimethylaminopropyl acrylamide. However, Horl et al. does in fact set forth the use of monomers of acrylic and methacrylic acid (C6/L26-30) and further sets forth the use of dimethylaminopropyl methacrylamide (C6/L41-42). Accordingly, dimethylaminopropyl

methacrylamide and dimethylaminopropyl acrylamide have art recognized equivalent function and properties such that they have become recognized as similar equivalents (see Galleguillos et al., USP 6361768 as evidentiary in column 6 where both are recognized as functional cationic monomers). It would have been obvious to one of ordinary skill in the art at the time of the invention to use dimethylamionpropyl acrylamide instead of dimethylaminopropyl methacrylamide as the art recognizes the equivalence of the two compounds and the selection of any known equivalent would have been within the level of ordinary skill in the art.

9. Claims 67-70, 72, 76, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horl et al. (USP 5,556,708), in view of Pitt et al. (USP 5,037,656), and further in view of Bell et al. (USP 6,774,102).

Regarding claims 67-69 modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. does not explicitly set forth the use of the separating material as for endotoxin removal from blood or affinity adsorption applications.

Bell et al. discloses a blood treating material to remove endotoxins by adsorption (abstract) using a polydisperse amino hollow fiber or activated polymer beads (C6/L35-60) and specifically affinity adsorption (C3/L25-45).

Horl et al. and Bell et al. are combinable because they are concerned with the same field of endeavor, namely that of amino functional polymers.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify use the separation material produced by Horl et al. as a hollow fiber

or bead for removal of endotoxins via affinity adsorption as taught by Bell et al. for the purpose of improved blood endotoxin removal.

Regarding claim 70, modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. does not explicitly set forth the use of the separating material as beads in a separating column.

Bell et al. discloses a blood treating material to remove endotoxins by adsorption (abstract) using a polydisperse amino hollowfiber or activated polymer beads (C6/L35-60) and specifically affinity adsorption (C3/L25-45). Bell et al. further discloses packing the beads into polycarbonate columns for blood purification (C7/L15-40).

Horl et al. and Bell et al. are combinable because they are concerned with the same field of endeavor, namely that of amino functional polymers.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify use the separation material produced by Horl et al. as a bead for removal of endotoxins via affinity adsorption in a separation column as taught by Bell et al. for the purpose of improved blood endotoxin removal.

Regarding claims 72, 76, and 83, modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. further discloses the membrane is fibrous (C7/L1-15).

Bell et al. discloses a blood treating material to remove endotoxins by adsorption (abstract) using a polydisperse amino hollowfiber polymer(C6/L35-60) and specifically affinity adsorption (C3/L25-45).

Horl et al. and Bell et al. are combinable because they are concerned with the same field of endeavor, namely that of amino functional polymers.

It would have been obvious to one having ordinary skill in the art at the time of the invention to utilize the fiber based separation material of Horl et al. and form hollow fiber membranes as taught by Bell et al. for the purpose of blood filtration.

10. Claim 71 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horl et al. (USP 5,556,708), in view of Pitt et al. (USP 5,037,656), and further in view of Duggins (USP 4,668,399).

Regarding claim 71, modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. does not explicitly disclose a separating cartridge with a tube, and potting hollow fibers in it.

Duggins discloses a hollow fiber plasmapheresis module in figures 1-3 comprising a hollow fiber membrane module (14) which is shown in figure 3 as a tube with hollow fibers in it. Furthermore, it is well known that in hollow fiber membrane modules, the fibers are potted to secure them.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the hollow fiber membrane of modified Horl et al. in a hollow fiber membrane module as taught by Duggins for the purpose of plasmapheresis.

11. Claims 73-75, 77-79, 86-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horl et al. (USP 5,556,708), in view of Pitt et al. (USP 5,037,656), and further in view of Steuck (4,618,533).

Regarding claims 73-74, 77-78, and 86-87, modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. does not explicitly set forth the use of copolymers that are hydrophilizing.

Steuck discloses a composite porous membrane formed from a porous polymeric membrane (abstract) which is exposed to a monomer and an initiator (C3/L45-66) wherein hydrophilizing copolymers are utilized as the substrate (C2/L60-C3/L11).

Horl et al. and Bell et al. are combinable because they are concerned with the same field of endeavor, namely that of thermally labile polymer radical grafting.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the polymer membrane of Horl et al. such that the substrate is formed from a hydrophilic copolymer as taught by Bell et al. for the purpose of improving the separation capacity and increasing the water affinity.

Regarding claims 75, 79 and 89, Horl et al. as modified does not explicitly set forth the use of PVP or PEO. However, Steuck does in fact set forth the use of related materials. Accordingly, PVP and PEO have art recognized equivalent function and properties such that they have become recognized as similar equivalents. It would have been obvious to one of ordinary skill in the art at the time of the invention to use PVP or PEO as hydrophilizing polymers as the art recognizes the equivalence of the two compounds and the selection of any known equivalent would have been within the level of ordinary skill in the art.

Response to Arguments

12. Applicant's arguments filed 2/11/2011 have been fully considered but they are not persuasive.

Applicant alleges non-obviousness in light of the failure of both references to provide enumerated examples that may be explicitly and directly linked to the instant claimed (e.g. Horl and Pitt fail to discuss an example using primary amino groups).

This is not persuasive. The lack of examples does not prove non-obviousness. A reference is taken for all that it teaches.

Applicant argues that the mechanism of Horl is unknown.

Horl is silent as to the specific reaction mechanism. However, See Drumheller for evidence at P7. Horl performs reaction using rongalite which is related to formaldehyde as discussed in Drumheller. Horl is in fact performing a reductive amination which is considered equivalent and or interchangeable in this instance with a thermally labile radical initation process. Additionally, the Horl reference and the Pitt references would both inherently form intermediary products along the way to forming the final material. If Applicant disagrees with an argument of inherency, Applicant should submit evidence, made of record, showing that the intermediate would not inherently occur.

The argument that Horl doesn't explicitly disclose grafting onto primary amino groups is not persuasive. Horl inherently when using the primary amino substrate would have this happen.

Further arguments to the lack of mechanistic explanation in Horl are considered moot in view of the above discussion and the Drumheller evidence.

Arguments regarding the presence or non-presence of CCl4 are not commensurate with the scope of the instant claims.

With regards to Pitt, the mechanism would inherently result in covalent coupling followed by graft copolymerization. Additionally, using the starting material of Horl would further provide for this inherent occurrence.

Pitt's absence of disclosure of intermediate binding moiety does not provide for non-obviousness. The reactants of Pitt would inherently absent **evidence** provide for an intermediary reaction product which would then form the final graft copolymer.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID C. MELLON whose telephone number is (571)270-7074. The examiner can normally be reached on Monday through Thursday 9:00am-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tony G Soohoo/
Primary Examiner, Art Unit 1774

/D. C. M./
Examiner, Art Unit 1777